



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application

Applicant : Tamea Rae Sisco  
Application No. : 10/025,273  
Filed : 12/18/2001  
Title : High Potency Clinical Anti-Craving Treatment and Method of Use  
Group Art Unit : 1617  
Examiner : Webman, Edward J.  
Attorney Docket No. : 123p-Real

The Honorable Commissioner of Patents and Trademarks  
Alexandria, VA 22313-1450

The Honorable Edward J. Webman  
Alexandria, VA 22313-1450

**AMENDMENT, TRAVERSE, ELECTION AND RESPONSE**

Honorable Mr. Commissioner,

Honorable Mr. Webman,

This paper is filed in response to the OFFICE ACTION mailed 02/23/2004, having therein a RESTRICTION REQUIREMENT.

**ELECTION**

**The applicant elects species I, claims 1 through 27, 29, and 34 through 39, drawn to a composition.**

In regard to species number II, a separate filing in a separate envelope of a new daughter application, claiming the benefit of this application, may be made by the applicant at a later date.

The applicant presently elects sub-option D, covered by claims 1 through 29, (claim 28 excluded) for components one, two and three, in response to the examiner's second level restriction requirement.

### **AMENDMENT**

In order to greatly simplify prosecution of the present case, the applicant hereby submits proposed amendments to the claims which remove certain sub-sub-species distinctions the examiner presently feels to be patentably distinct in a third level restriction requirement.

More generally, certain other claims are withdrawn in accordance with other restriction requirements made by the examiner, without prejudice to re-presentation at a later date or in other proceedings before the patent office.

### **RESPONSE and TRAVERSE**

1. FIRST AND SECOND LEVEL RESTRICTION REQUIREMENTS (Pages 1 and 2 of the FIRST OFFICE ACTION)

The examiner has entered a first restriction requirement, either to the composition of

claims 1-29 (species I), or to the method of administration (remaining claims) (species II). The applicant has herein elected species I, without conceding the necessity for the requirement. Other claims are presently withdrawn without prejudice to further prosecution.

The examiner has further required restriction to one choice of sub-species A, B, C or D. The applicant has herein elected sub-species D without conceding the necessity for the requirement and without prejudice to further prosecution.

2. THIRD LEVEL ELECTION REQUIREMENT (Pages 2 through 6 of the FIRST OFFICE ACTION)

The examiner has cited claims 9, 16 and 21 as requiring further restriction, in other words restriction to the level of sub-sub-species, presumably based upon the assumption that each individual selection of possible subcomponents of the composition is uniquely patentable. Applicant respectfully urges that all claims as drawn distinctly claim and particularly point out the subject matter of the invention, which is a combined effect of administration of a number of different amino acids, vitamins and minerals at one time. Finally, in order to moot this issue entirely, the applicant has made claim amendments to simplify and broaden the claim language.

The applicant is furthermore aware that “Markush” groups in claims (“... one member selected from the group consisting of: . . . , and combinations thereof”) normally pose a burden in terms of determining all possible combinations of members of such a group. The examiner alludes to this indirectly by using the phrase (for example on page 4 of the First Office Action

discussing claim 16) “species comprising one to six minerals”. With utmost respect, the applicant points out that this is erroneous. In the present case the unusual form of these claims is such that efficiency is actually served by not breaking the claims down into an unwieldy number of individual claims. A number of claims of the invention, including claims 9, 16 and 21, are drawn up in an unusual variation on the “Markush” format, claiming multiple members selected from groups consisting of a number of possible chemicals, rather than a single member of such groups. For example, claim 6 states “at least five members selected from the group consisting of:... (six minerals acids)”. The applicant does NOT intend to claim single members of these groups. Thus the claim as originally presented actually covers only 6 combinations of minerals, (each having omission of one element) while breaking them down individually according to the examiner’s (natural and usual) interpretation would result in five factorial combinations of minerals (720 combinations each having from one to six possible components). Thus the applicant’s Markush terminology very greatly simplifies prosecution.

On the contrary, the invention consists of the administration of a number of such items at the same time, and the individual sub-sub-species will typically vary from other members of the sub-species by only the removal of one member and the substitution of another.

In accordance with the examiner’s request that the applicant point to evidence in the record that such is the case, the applicant provides the following quotes from the originally filed application, all to the effect that simultaneous administration of a spectrum of ingredients is desirable.

Page 27, line 15 et seq:

As stated previously, the brain's neurotransmission system is quite complex, featuring large numbers of interrelationships of neurotransmitters, pro-neurotransmitters, amino-acids, minerals, vitamins, and metabolites of these, all acting simultaneously on various different areas of the brain. Thus, anti-craving medications may have several agents which attempt to achieve the necessary synergistic effects in the brain, that is, all agents should be present, at the right time and in the proper, cellularly active forms, for maximum effectiveness. The synergistic effects of having, for example, a pro-neurotransmitter, a mineral helpful for its passage of the blood/brain baffle, and a vitamin which regulates the enzymes which break down the desired neurotransmitter are well recognized.

Page 7, line 20 et seq.:

In greater detail: the reward/pleasure response in the brain is a complex process in which stimulus in one part of the brain controls stimulus in others, which may in turn lead to stimulation of yet another part of the brain. Each of the steps of release, reception or uptake of neurotransmitters takes place at simultaneously at different locations, and for different substances, and different steps in the neurotransmission cycle may be under the influence of different neurotransmitters or other biochemicals: the release, reception or uptake of neurotransmitters is frequently under the control of other substances: amino-acids,

vitamins and minerals. A short example is provided: a low level of a neurotransmitter in the brain can be partially or wholly offset by application of precursor amino-acids which help to build up the level. However, the level of the precursor amino-acids in the brain may be determined by their ability to cross the blood/brain barrier, which in turn may be governed by the amount of a given mineral in the blood stream. The rate of breakdown and maintenance of the same neurotransmitter in the brain may also be effected or even controlled at that point by the availability of some vitamin or mineral in the system acting upon the enzyme controlling the neurotransmitter. And a mineral which promotes the crossing of the blood/brain barrier by one amino-acid might act to reduce the crossing of the same barrier by other amino-acids. To provide details of this short example: L- tryptophan is a precursor which promotes neurotransmitter activities, while D-phenylalanine promotes neurotransmitter activity by inhibiting enzymatic cleavage. Administration of niacinamide, a form of the vitamin niacin, reduces the premature breakdown of L-tryptophan in the blood stream because tryptophan is typically used in a 60 to 1 ratio to produce niacinamide. Niacinamide later appears to reduce the rate of serotonin breakdown in the brain by inhibiting the action of tyrtophan pyrrolase. The mineral calcium assists L-tryptophan to enter the brain, and then further assists conversion of tryptophan to serotonin, but drives other amino-acids into muscle tissue instead. L-tryptophan is desired for its ability to elevate serotonin levels, act as asleep agent, and reduce depression. When a patient is sleeping well and not depressed, the L-tryptophan may actually be

removed from alternative embodiments of the present invention. Obviously while L-tryptophan is desirable, it is not desirable to encourage L-tryptophan's action at the expense of the other amino-acids used in the present invention. There are literally hundreds of such interactions taking place, creating a system too complex for present day modeling techniques to interpret.

Thus formulation of amino-acid based anti-craving medications is an unpredictable task, and anti-craving medications tend to involve a spectrum of ingredients designed to assist the combined efficacy or efficiency of the anti-craving effect.

The examiner will recall that these arguments in favor of administration of multiple amino acids or multiple vitamins, etc, are only a small part of the overall application, which deals as well with issues of metabolic bypass in the heavily damaged internal organs of substance abusers, practical compounding issues and so on.

For all of these reasons, the applicant very respectfully does not concede that the different embodiments warrant the third level restriction/election requirement.

In order to moot the issue presented, the applicant is taking the following steps.

At the present time, the applicant proposes a simple amendment to claims 9, 16 and 21 which should obviate this issue. In each case, the language is simplified by removal of the list of potential ingredients and the substitution of a number such as "at least three amino-acids". The issue of sub-sub-species thus disappears as a single limitation is provided instead of the lists of potential medicinal ingredients.

Following up at a later date, the applicant will submit a CIP application offering the formulation of one or more embodiments more specifically, hopefully in a manner which will meet the examiner's approval in that later proceeding.

For all the foregoing reasons, applicant respectfully urges that the elected claims of the application are now in condition for immediate allowance, and such action is requested. The examiner is respectfully urged to contact applicant's attorney with any questions or comments at Craig W. Barber, at 303-278-9973 or 303-279-6106, or by mail to: The Law Office of Craig W. Barber, PO Box 16220, Golden, Colorado, USA 80402-6004, with any questions or comments.

Signed: 

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